

REMARKS

The present application is directed to methods, devices, and kits for the detection, isolation or purification of an analyte in a sample. In particular, the application relates to the detection, isolation or purification of a bacteria using a device or kit having a separable detection zone.

Claims 1, 9, 10, 21, 26, 29 and 30 are currently amended. Claims 8, 12, 17-19 and 27-28 are cancelled without prejudice. Claims 1-7, 9-11, 13-16, 20-26 and 29-30 are pending. Favorable consideration of the currently pending claims is respectfully requested in light of the following amendments and remarks. No new matter is added and support for the amendments may be found throughout the specification and original claims.

Claim rejections under 35 U.S.C. § 112, second paragraph.

In the Office Action mailed July 19, 2006, the Examiner rejected Claims 21 and 26-30 under 35 U.S.C. § 112, second paragraph as indefinite. Applicant respectfully submits that amendments to the claims overcome the rejection.

Applicant has amended Claim 21 to recite “and” between the last two elements of the Markush group, as suggest by the Examiner.

Claim 26 has been amended to clarify the preamble of the claim, as suggested by the Examiner.

Accordingly, applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Claim rejections under 35 U.S.C. § 102(b)

In the Office Action mailed July 19, 2006, the Examiner rejected Claims 9, 10 and 20 under 35 U.S.C. § 102(b) as being anticipated by Noda *et al.* (U.S. Patent No. 5,900,379; Noda). Applicant respectfully submits that amendments to the claims overcome the rejection.

Claims 9 and 10 have been amended to recite a kit and device for detecting an analyte, wherein the analyte is a **bacteria**. Support for this limitation can be found on, at least, page 4, lines 25-29 of the instant application.

In contrast, Noda is directed to the collection and storage of **biological fluids**, such as urine (see abstract). Applicant respectfully submits that Noda fails to teach or suggest the detection of **bacteria** in the detection zone area (membrane immunoassay – see element 2 of drawings) of the analytical device. In fact, Noda **teaches away** from the detection of bacteria in the detection zone of the analytical device. Noda consider bacteria contaminants and warrants their disposal from biological fluids. Column 5, lines 39-44 of Noda recites, “For example, growth in the absorbent material of microorganisms present in the urine can be prevented because the absorbent material can be easily removed from the cassette.” Therefore, applicant respectfully submits that Noda fails to teach or suggest the claimed kit or device.

Claim 10 recites a device in which binding between the immobilized binding partner and a suspected analyte causes formation of an optically detectable signal. Support for this limitation can be found on, at least, page 10, lines 2-3. Applicants respectfully submit that Noda fails to teach or suggest detection of a signal by an optically detectable signal as claimed in Claim 10 and certainly fails to teach detection by a light signal as set forth in amended Claim 30. Applicants submit that Claim 9 depends from amended Claim 1 and is therefore also novel in view of Noda.

Accordingly, applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §102(b).

Claim rejections under 35 U.S.C. § 103(a)

In the Office Action of July 19, 2006, the Examiner rejected Claims 1-7, 9-16 and 20-30 under 35 U.S.C. §103(a) as being unpatentable over LaBorde (U.S. Patent No. 6,607,922)

in view of Benjamin *et al.* (U.S. Patent No. 5,491,068; Benjamin). Applicant respectfully submits that the amendments to the claims overcome the rejection.

LaBorde teaches a test strip having a porous membrane (element 13) that includes a capture zone (element 14), a backing member (element 12) and a **protective member** (opaque surface or cover; see element 15 of drawings). LaBorde deems the protective member **critical** because, without the protective surface, the porous nitrocellulose membrane would be **damaged** by rubbing across the detection coil (34), thereby producing **incorrect** or **unreliable readings**, or both (see column 6, lines 6-12 and Abstract). Applicant respectfully submits that the use of a protective member over the detection zone, as taught by LaBorde, would impede one's ability to remove the detection zone as claimed herein.

Additionally, Claims 1 and 10 have been amended to recite detection of bacteria by an optically detectable signal. In contrast, LaBorde uses superparamagnetic particles to detect target analytes, which in turn requires an **electromagnetic reader** (see Abstract).

Applicant submits that the deficiencies of LaBorde are not satisfied by Benjamin for at least the following reasons. Benjamin fails to teach a method, kit or device in which the signal is detected by an optically detectable signal. Benjamin discloses **magnetic beads** having immobilized antibodies. As discussed above with respect to LaBorde, the magnetic beads of Benjamin are exposed to a **magnetic field**. Neither LaBorde nor Benjamin teach or suggest detection of a signal via an optically detectable signal as claimed herein.

For at least the foregoing reasons, applicant submits that the amended claims are nonobvious to one of ordinary skill in the art at the time the invention was made in view of the cited references, alone or in combination. Accordingly, applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 103(a).

CONCLUSION


Based upon the amendments and remarks provided above, applicant believes that the pending claims are in condition for allowance. A Notice of Allowance is therefore respectfully solicited.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Please charge any additional fees, or credit any overpayment, to Deposit Account 11-0855.

Respectfully submitted,


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